COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
PETER S. PEARLMAN
Park 80 Plaza West-One
250 Pehle Avenue, Suite 401
Saddle Brook, NJ 07663
201-845-9600
psp@njlawfirm.com

Attorney for Plaintiff
[Additional Counsel appear on signature page.]

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LOUISIANA WHOLESALE DRUG CO., INC., on behalf of itself and all others similarly situated, **Plaintiff,** **V.** **SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHAMACEUTICALS** **Defendants.**	**Civil Action No. _____** **JURY TRIAL DEMANDED** **CLASS ACTION COMPLAINT**

Plaintiff, Louisiana Wholesale Drug Co., Inc. ("Plaintiff" or "LWD"), 2085 I-49 South Service Road, Sunset, Louisiana 70584, on behalf of itself and all others similarly situated, for their Complaint against Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), One Franklin Plaza, Philadelphia, Pennsylvania 19102; and Defendants Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel, and its subsidiary Teva Pharmaceuticals USA, Inc. ("Teva USA" and, collectively

with Teva Ltd., "Teva"), 1090 Horsham Road, North Wales, Pennsylvania 19454, allege as follows based on: (a) personal knowledge; (b) the investigations of counsel, including review of various pleadings and rulings in *SmithKline Beecham Corp. v. Teva Pharmaceuticals USA, Inc.*, United States District Court, District of New Jersey, Nos. 02-cv-3779 and 02-cv-4537, and *Teva Pharmaceutical Industries Ltd, et. al v. SmithKline Beecham Corporation*, United States District Court, District of New Jersey, No. 08-cv-03706, discussed herein; and (c) information and belief:

I. NATURE OF THE ACTION

1. This case is brought on behalf of LWD and a class of all other persons or entities in the United States who directly purchased Lamictal brand lamotrigine tablets ("Lamictal Tablets") from GSK and/or a generic version of Lamictal Tablets from Teva at any time during the Class Period of February 17, 2008 until the effects of Defendants' conduct ceases (the "Class").

2. Since 1994, GSK has manufactured and sold Lamictal Tablets for the treatment of epilepsy, bipolar disorder and other medical conditions. For the twelve months ending March of 2008, GSK's sales of Lamictal Tablets in the United States exceeded $2 billion. GSK also markets Lamictal chewable dispersible tablets ("Lamictal Chewables"), which is a low-dosage strength chewable lamotrigine tablet, with annual domestic sales of only about $50 million during the same time period.

3. For a period of time, GSK had various exclusivities that protected both Lamictal Tablets and Lamictal Chewables from less-expensive generic competition. For purposes of this case, the primary exclusivity stemmed from U.S. Patent No. 4,602,017 ("the '017 patent") which GSK listed in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Lamictal Tablets and Lamictal Chewables. This patent had an expiration

date in July 2008. In addition, GSK was also granted a six-month Pediatric Exclusivity on its Lamictal Tablets in 2007. Pediatric Exclusivity attaches to, among other things, the end of any valid and infringed patent. No relevant regulatory exclusivities extended the life of the '017 patent itself per se.

4. In 2002, Teva, the largest generic pharmaceutical company in the United States and the world, filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval to market both Lamictal Tablets and Lamictal Chewables. These ANDAs were accompanied by what is called in the industry "paragraph IV certifications," stating that the ANDA products did not infringe any valid or otherwise enforceable patent(s) listed in the Orange Book as pertaining to Lamictal Tablets or Lamictal Chewables. Teva sent notices of the paragraph IV certifications to GSK, along with detailed statements as to how it was that their ANDA products did not infringe any applicable valid or otherwise enforceable patent(s) listed on the Orange Book as pertaining to either of the two referenced listed drugs.

5. Because Teva was the first paragraph IV ANDA filer, Teva gained the extremely valuable exclusive right to potentially sell its less-expensive generic versions of both Lamictal Tablets and Lamictal Chewables for a period of 180 days, during which the FDA would not give final approval to any other manufacturer's competing generic ANDA-based products. Being the first paragraph IV filer potentially gave Teva a significant and highly profitable competitive advantage since it might be the only generic in the market for each of the two products for six months, during which Teva would not only garner huge sales volumes but also charge higher prices because it would not be facing any generic competition. Furthermore, it is well-known in the industry that those generics which are able to take advantage of the 180-day exclusivity

periods are able to get a "first mover advantage" resulting in the permanent retention of a larger market share even after other generics enter the market.

6. Under applicable FDA regulations, the start of Teva's 180-day exclusivity period could be triggered by either: (1) Teva's first commercial launch of either generic product, although a launch of generic Lamictal Tablets would not trigger the 180-day period on generic Lamictal Chewables, and vice versa; or (2) with respect to the exclusivity pertaining to generic versions of Lamictal Tablets, the entry of a final court decision declaring the '017 patent invalid or not infringed, regardless of whether or not Teva had commenced sales.

7. In 2002, GSK sued Teva over both Lamictal Tablets and Lamictal Chewables alleging willful infringement of the '017 patent, and these cases were subsequently consolidated (the "Patent Litigation"). The Patent Litigation eventually proceeded to a five-day bench trial in January of 2005. On the final day of trial, presiding Judge Bissell issued a bench ruling invalidating the independent claim (claim 1) of the '017 patent. He additionally informed the parties that a ruling on the validity of the remaining three claims at issue (all of them dependent claims) would be forthcoming.

8. Faced with the danger that the court might invalidate the '017 patent (which would also prevent Pediatric Exclusivity from attaching to the end of that patent), GSK faced the risk of a dramatic reduction in future revenue due to the loss of exclusivity of both Lamictal Tablets and Lamictal Chewables. The very reasonable possibility that Teva might win the patent case also placed Teva in a quandary regarding its desire to maximize the use of its 180-day exclusivity period for its generic equivalent of the more lucrative Lamictal Tablet products. At the time of the patent trial, Teva had not received either final or tentative approval for its Lamictal Tablet ANDA. Thus, Teva was in a position where it could potentially win the '017

patent suit, at which point its 180-day period would begin for its generic Lamictal Tablets, but it might not be in a position to take advantage of all or part of that 180-day exclusivity by selling a generic Lamictal Tablet product during the exclusivity period. If Teva's 180-day exclusivity expired before its generic Lamictal Tablet product was approved for sale, other competitors with approved AB-rated equivalent generic Lamictal Tablet products might be able to enter the market at the same time as (or even before) Teva. Thus, GSK had an interest in delaying Teva's entry for as long as possible so that GSK could continue to earn monopoly profits on both Lamictal Tablets and Lamictal Chewables – with the more than $2 billion a year Lamictal Tablets product constituting GSK's chief concern. Teva also had an interest in preventing and/or delaying a successful final court decision until it would be in a position to take advantage of its valuable 180-day exclusivity on its generic version of Lamictal Tablets.

9. Recognizing the severe financial risks to both parties (i.e., that GSK might lose its patent protection entirely and that Teva might not be ready to take advantage of its success), the parties started settlement negotiations in early February 2005 soon after the trial was over and asked the court to refrain from ruling on the validity of the remaining patent claims.

10. Later that month, the parties entered into anticompetitive settlement and license/supply agreements. These agreements, which are both expressly acknowledged by GSK and Teva to be part of the "consideration" that GSK offered Teva" in reaching agreement to settle", were beneficial to GSK and Teva in that they delayed market entry of less-expensive generic versions of Lamictal Tablets, but at the same time guaranteed Teva's ability to make use of its 180-day exclusivity period for its generic Lamictal Tablets, thereby maximizing the profits of both. The settlement and license/supply agreements caused illegal anticompetitive harm to purchasers of Lamictal Tablets and/or Teva's generic version of Lamical Tablets by causing

them to pay higher, artificially-inflated prices for those products than they otherwise would have absent the conduct alleged herein.

11. In April 2005, the parties submitted a Stipulation and Order of Dismissal in the '017 Patent Litigation, and the court withdrew its earlier bench ruling that invalidated claim 1 of the '017 patent.

12. Under the agreements, Teva agreed to not enter the market with a generic version of GSK's $2 billion Lamictal Tablet product until as late as the July 2008 expiration date of the '017 patent. Thus, even though Teva had already succeeded in invalidating the '017 patent's primary, independent claim, and even though there was a significant risk that the patent's other claims might be invalidated, the settlement gave little or no discount or reduction to the patent's exclusionary power (i.e., it did not give Teva the right to enter significantly prior to the patent's expiration).

13. In exchange for this delayed entry regarding generic Lamictal Tablets, Teva received various illegal financial inducements. First, Teva was permitted to sell limited amounts of a generic version of the much smaller, $50 million per year Lamictal Chewable product in the U.S., starting in June 2005. In pleadings from a subsequent litigation between the parties, GSK has acknowledged that Teva's right to enter in June 2005 with a generic version of the much smaller Lamictal Chewable product was a benefit given to Teva for agreeing to the later July 2008 entry date for the lucrative Lamictal Tablet product. Even though both the Lamictal Tablet and Lamictal Chewable products were subject to the same patent claims – and Teva's chances of litigation success were the same for both products – Teva and GSK agreed that Teva would enter the market for the smaller Lamictal Chewable product three months after the settlement, but that Teva would wait three years or longer to enter regarding the forty-times larger Lamictal Tablet

product. The disparate treatment and entry dates that GSK and Teva negotiated for the two products (both of which were subject to the exact same patent claims and litigation risks) reflects the fact that the parties did not choose (or even attempt to choose) entry dates for the two products that reasonably reflected the probability that the '017 patent was invalid. If there was a significant probability that the '017 was invalid then the parties should have agreed that Teva could start selling both products in or about three months after the settlement, and conversely, if there was a significant probability that the patent was valid then that should have been reflected by an agreement that Teva would have to wait a longer period of time to enter the market for both products. The fact that the entry dates were so significantly different reflects the fact that the parties were not concerned about whether Teva would successfully invalidate all asserted claims of the patent and/or whether the agreement would keep Teva off the market for the larger product longer than was warranted by the patent. Rather, it reflects the reality that Teva was paid financial compensation to delay entry of its generic Lamictal Tablet product. Furthermore, while the negotiated deal benefitted Teva and GSK, it was not done with any concern or interest for purchasers or consumers who need treatment for epilepsy, bipolar disorder and other medical conditions. The purchaser/consumer benefits gained by the early generic Lamictal Chewable entry date of June 2005 pale in comparison to the purchaser/consumer harm incurred by the anticompetitive three-year delay in the entry of Teva's less-expensive generic version of Lamictal Tablets.

14. Teva's second financial inducement for agreeing to give GSK the full protection of the '017 patent regarding Lamictal Tablets was that Teva would be virtually guaranteed the right to use most, if not all, of its 180-day exclusivity period for that product, which would enable it to charge higher prices during the first 180 days, and to maximize its longer-term

profits by obtaining the "first move advantage" noted above. This also benefitted GSK since the fact that Teva would charge higher prices during the first 180 days meant that there would be less competitive pressure on GSK during this period, such that it would lose less market share during this period than if there were multiple generics in the market during the period. GSK also benefitted in a broader sense in that the agreements as a whole delayed not only the entry of Teva's generic Lamictal Tablet products, but other generics as well. Thus, by and through these agreements, Teva and GSK afforded themselves a guarantee of higher revenues during these periods of time which resulted in anticompetitive overcharges being thrust upon purchasers.

15. In addition, Teva's right to 180 days of generic exclusivity as the first ANDA filer for generic versions of both Lamictal Tablets and Lamictal Chewables did not bar GSK from launching its own generic version of the subject product during Teva's exclusivity periods (known in the industry as as "authorized generic"). Upon information and belief, Teva obtained a third inducement to delay its entry of generic Lamictal Tablets in that Teva and GSK illegally agreed that GSK would refrain from competing against Teva during the first 180 days by launching an authorized generic version of both the Lamictal Tablets and the Lamictal Chewables. While Teva's 180-day exclusivity gave it the highly lucrative ability to sell both generic Lamictal Tablets and Lamictal Chewables without competition from other generic manufacturers seeking to market their products by and through ANDAs, the defendants recognized that that valuable opportunity could be significantly reduced if GSK chose to launch its own authorized generic during the first 180 days, which is a common strategy in the pharmaceutical industry. An authorized generic is simply the brand product sold under generic trade dress at a cheaper price than the brand. As of 2005, GSK had a history of launching

authorized generic versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics.

16. The Federal Trade Commission ("FTC") and other government entities have recognized that the presence of an authorized generic significantly benefits purchasers by both increasing purchaser choices and also creating price competition which reduces generic prices during the first 180 days. By agreeing to not exercise its lawful right to launch an authorized generic during the first 180 days, GSK was agreeing to restrain or limit its ability to compete during this period. This would increase Teva's unit sales and pricing power to the detriment of Lamictal Tablet purchasers. As alleged in more detail below, Teva has admitted that the illegal agreement that GSK would not launch an authorized generic of its own was a significant consideration that was "critical here because the benefit conferred to Teva from this Settlement was of such a short duration," referring to its delayed July 2008 entry of generic Lamictal Tablets.

17. Thus, absent the payment of the anticompetitive inducements, noted above, from GSK to Teva to delay the launch of its generic version of Lamictal Tablets, Teva would have pressed for (and the parties would have agreed to) a settlement allowing Teva to come to market with its generic Lamictal Tablets earlier than the settlement agreements allowed. Alternatively, and upon information and belief, absent a settlement, the parties would have continued to litigate, and Teva's success would have allowed for an earlier launch of generic versions of Lamictal Tablets after finalization of the patent case, or allowed for an at-risk launch by Teva of its generic version of Lamictal Tablets during the litigation after Teva received final approval from FDA. Regarding both entry scenarios alleged above, it is well known in the industry that Teva is the most prolific launcher of generic versions of brand-name drugs "at-risk," that

launching at-risk is a core part of its business strategy, that Teva possesses insurance covering portions of this risk, and that as a multibillion-dollar-a-year company Teva possesses the financial horsepower above and beyond "at-risk" insurance to cover potentially non-insured losses stemming from at-risk launches. It is also well known that most at-risk launches, or threats of them, generally give rise to settlements of the associated patent litigation.

18. Plaintiff, and all others similarly situated, were injured and sustained damages in the form of overcharges for branded and generic forms of Lamictal Tablets as a direct result of GSK and Teva's unlawful agreements that accompanied the settlement of the '017 patent litigation.

II. JURISDICTION AND VENUE

19. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the injuries sustained by Plaintiff and members of the Class resulting from violations by the Defendants, as hereinafter alleged, of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

20. The Defendants named herein are found or transact business within this judicial district, and the interstate trade and commerce hereinafter described is carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).

III. THE PARTIES

21. Plaintiff LWD is a corporation organized under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584. LWD purchased branded and generic Lamictal Tablets directly from GSK and Teva during the Class Period as defined below, and was injured by the illegal conduct described herein.

22. On information and belief, Defendant SmithKline Beecham Corporation is a private corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having a registered office at One Franklin Plaza, Philadelphia, Pennsylvania 19102. SmithKline Beecham Corporation operates under the business name GlaxoSmithKline. GSK is in the business, among other things, of developing, manufacturing, distributing, advertising, and selling the Lamictal products throughout the United States.

23. Defendant Teva Ltd. is a corporation organized and existing under the laws of the State of Israel and having registered office at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel. Teva Ltd. is the ultimate parent company of Teva USA.

24. Defendant Teva USA is incorporated under the laws of the State of Delaware, with its principal place of business in North Wales, Pennsylvania. Teva USA develops, manufactures, and sells generic products in the United States. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

25. Teva Ltd. manufactures the generic lamotrigine tablet product that Teva USA began selling in the United States in July of 2008.

IV. CLASS ACTION ALLEGATIONS

26. Plaintiff brings this action on behalf of itself and, under Rule 23 of the Federal Rules of Civil Procedure, as representative of a class defined as follows:

> All persons or entities in the United States and its territories who directly purchased Lamictal Tablets from GSK, or who directly purchased a generic version of Lamictal Tablets from Teva, at any time during the Class Period of February 17, 2008 until the effects of Defendants' conduct ceases (the "Class"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

27. Members of the Class are so numerous that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff, it is believed to be at least in the hundreds. Furthermore, the Class is readily identifiable from information and records in the possession of Defendants.

28. Plaintiff's claims are typical of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by the Defendants; i.e., they have paid artificially inflated prices for Lamictal Tablets and were deprived of the benefits of competition from less-expensive generic versions of Lamictal Tablets as a result of Defendants' anticompetitive conduct.

29. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

30. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, particularly class action antitrust litigation in the pharmaceutical industry.

31. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because the Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

32. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. whether a relevant market needs to be defined in this case in light of the existence of direct evidence of GSK's power to exclude generic competition and charge supra-competitive prices for Lamictal Tablets;

c. if a relevant market needs to be defined, the definition of the relevant market for analyzing GSK's monopoly power, and whether GSK had monopoly power in the relevant market;

d. whether Defendants' actions illegally maintained Defendants' monopoly power in the relevant market;

e. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

f. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers and if so, the appropriate measure of damages.

33. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously,

efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that may not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

34. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY AND ECONOMIC BACKGROUND

35. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) a manufacturer who creates a new, pioneer drug must obtain the approval of the Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents. A manufacturer may only promote uses for a drug that are approved by the FDA.

36. In 1984, Congress amended the Food, Drug and Cosmetics Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

37. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an ANDA.

38. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer must show the FDA that

the generic drug it is going to market is just as safe and just as effective as the corresponding brand-name drug through demonstrations of bioequivalence. A demonstration of bioequivalence means that, within certain set parameters of variability, the generic product delivers the same amount of active ingredient into the patient's blood stream for the same amount of time as does the corresponding brand drug. The range of acceptable variability afforded to generic drugs for demonstrating bioequivalence is the same lot-to-lot (i.e., batch-to-batch) range of variability afforded to brand companies when manufacturing their own brand drug.

39. Generally speaking, ANDA filers are seeking to have their generic products deemed to be "AB-rated." AB-rated generics have been determined by the FDA to be therapeutically equivalent (i.e., bioequivalent) and pharmaceutically equivalent to their brand-name counterparts. Pharmaceutical equivalence means the two drugs have, among other things, the same active ingredient, same strength, same route of administration, and same dosage form.

40. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

41. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (i.e., the Hatch-Waxman Act) and most state legislatures (i.e., Drug Product Selection, or "DPS laws"), pharmacists may (and, in most states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking

or obtaining permission from the prescribing doctor (unless the prescription is denominated "Dispense as Written," or "DAW"). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously (a) engaging in the type of heavy promotion or "detailing" typically done by brand-name manufacturers, and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

42. AB-rated generic competition enables direct purchasers to: (a) purchase generic versions of brand-name drugs at substantially lower prices; and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug which competes with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong incentive to use various tactics, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into the market.

43. As a counter-balance to the above-described benefits provided to generics, the Hatch-Waxman Act streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with what is essentially an automatic preliminary injunction, in the form of a 30-month stay of FDA approval of generic manufacturer's ANDAs.

44. When the FDA approves a brand-name manufacturer's NDA, the FDA publishes any patents which, according to information supplied to the FDA by the brand-name manufacturer, claim the approved drug or its approved uses, in the Orange Book. 21 U.S.C. §355(j)(7)(A)(iii). The FDA does not check the facts supplied to it by the brand-name

manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand-name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand-name manufacturer similarly certifies that the new patents claim either the approved drug or its approved uses.

45. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA does not violate any patent listed in the Orange Book as claiming the brand-name drug.

46. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

a. that no patent for the brand-name drug has been filed with the FDA;

b. that the patent for the brand-name drug has expired;

c. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "paragraph III certification"); or

d. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

21 U.S.C. §355(j)(2)(A)(vii).

47. Alternatively, an ANDA may assert that a patent is inapplicable to the indication for which the drug product will be marketed (called a "section viii statement").

48. If a generic manufacturer files only a paragraph III certification, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. §355(j)(5)(A). If the FDA approves the ANDA, the approval can become effective on the date certified as the patent expiration date. 21 U.S.C. §355(j)(5)(B)(ii).

49. If a generic manufacturer files a paragraph IV certification that the listed patent is invalid or will not be infringed, then the brand-name manufacturer has the opportunity to slow the process down. This is because a generic manufacturer filing a paragraph IV certification must promptly give notice of this fact to both the NDA owner and the owner(s) of the patent(s) at issue. The generic manufacturer's notice of the act of filing a paragraph IV certification triggers the time by which a patent owner may file an action for patent infringement, and take advantage of an automatic 30-month stay of FDA approval of the generic version of the NDA owner's drug.

50. If the patent owner fails to initiate a patent infringement action within 45 days after receiving notice of the generic manufacturer's paragraph IV certification, then the FDA may grant "final approval" to the generic manufacturer's ANDA immediately upon satisfying itself as to the bioequivalency of the generic to the brand-name drug. If, however, the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not grant final approval to the ANDA until the earlier of either 30 months after the brand company's receipt of the notice of paragraph IV certification or the issuance of a final decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §355(j)(5)(B)(iii).

51. In turn, the Hatch-Waxman Act encourages the challenge to branded drug patents and/or to design around them, by granting the first paragraph IV certification ANDA filer a 180-day period to exclusively market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. Under the regulations in place at the time Teva filed its ANDAs for generic versions of Lamictal Tablets and Lamictal Chewables here, this 180-day exclusivity period would not begin to run

until either the first ANDA applicant entered the market with its generic equivalent, or a court entered a final judgment that the patent(s) subject to paragraph IV certification were invalid and/or not infringed. 21 U.S.C. § 355(j)(B)(iv).

52. By and through these provisions, the Hatch-Waxman Act does not guarantee a paragraph IV first ANDA filer the right to make use of all or a portion of the 180-day exclusivity period. If the 180-day period is triggered, for instance, by a final court decision, but the ANDA first filer has not yet obtained final approval from FDA to market its generic product due to unrelated safety and/or efficacy issues, then it may well be that the 180-day period commences and elapses without the ANDA first filer enjoying any actual sales of its product during that time. In such an instance, however, a benefit is conferred to other ANDA filers and all purchasers in that, at the end of the 180-day period, any and all other ANDAs that are eligible to receive final approval may then come to market; thus giving rise to competition to the branded product, and resulting in lower prices to purchasers.

VI. FACTUAL ALLEGATIONS

A. The Parties' Products and the Nature of Sales of Generic Equivalent Products

53. GSK sells Lamictal Tablets in strengths of 25mg, 50mg, 100mg, 150mg, and 200mg pursuant to New Drug Application No. 20-241, which was approved by the FDA in 1994. GSK sells Lamictal Chewables in strengths of 2mg, 5mg and 25mg pursuant to New Drug Application No. 20-764, which was approved by the FDA in August of 1998. For the twelve months ending March of 2008, GSK's sales of Lamictal Tablets in the United States exceeded $2 billion, according to IMS data. The low-dosage strength Lamictal Chewable products had annual domestic sales of only about $50 million during the same time period.

54. Upon receiving FDA approval of its NDA for Lamictal Tablets on December 27, 1994, GSK was awarded a five-year new chemical entity ("NCE") exclusivity, which expired on or about December 27, 1999. During this five-year period, ANDAs could not be given final approval by the FDA, meaning GSK's Lamictal Tablets would be free from generic competition for at least a five-year period. Subsequently, GSK received approval for a new label indication for the adjunctive treatment of Lennox-Gastaut syndrome in pediatric and adult populations. As part of that approval, Lamictal Tablets was awarded a seven-year orphan drug exclusivity ("ODE"), commencing on August 24, 1998. Congress enacted the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1982), in order to encourage firms to develop pharmaceuticals to treat rare diseases and conditions. The Orphan Drug Act establishes a seven-year ODE period during which no ANDA for the same use of a generic version of the drug can be approved. 21 U.S.C. 360cc. However, ODE is indication-specific, meaning that the FDA can approve an ANDA for non-ODE protected uses during the seven-year period. The ODE for Lamictal Tablets expired on or about August 24, 2005, although Lamictal Tablets were approved for additional non-ODE protected indications, which allowed for ANDAs to be approved prior to this date.

55. The '017 patent, which expired on July 22, 2008, was (and has been) the only patent listed in the Orange Book for Lamictal Tablets. The '017 patent, along with another patent (U.S. Patent No. 5,698,226), was listed in the Orange Book as pertaining to Lamictal Chewables, although as alleged below, this second patent played no role in the patent litigation between GSK and Teva. In addition, in 2007 – well after execution of the agreements between GSK and Teva at issue here – GSK received a 6-month Pediatric Exclusivity, which did not extend the '017 patent's expiration date but did prevent any ANDA applicant for a product claimed by the '017 patent from receiving final regulatory approval of their ANDA until January 22, 2009, assuming

the '017 patent was not invalidated or there was a showing that a particular ANDA product did not infringe that patent.

56. On or about April 1, 2002, Teva filed ANDA No. 76-388, seeking approval to manufacture and sell a generic version of Lamictal Tablets. A short time later, Teva filed ANDA No. 76-420, seeking approval to manufacture and sell a generic version of Lamictal Chewables. Teva was the first to file substantially complete ANDAs for AB-rated generic equivalents to Lamictal Tablets and Lamictal Chewables, with paragraph IV certifications to the '017 patent. It also filed a paragraph IV certification to the second patent listed in the Orange Book regarding Lamictal Chewables. Accordingly, Teva was granted the potentially valuable 180-day exclusivity period for generic lamotrigine tablets and lamotrigine chewables, during which no other manufacturers could sell generic versions of Lamictal Tablets or Lamictal Chewables (except for GSK which had the legal right to sell authorized generic versions of the products). The FDA ultimately approved Teva's ANDA for lamotrigine chewables on June 21, 2006 and Teva's ANDA application for lamotrigine tablets on August 30, 2006. In so doing, the FDA found that: (a) Teva's lamotrigine chewables are bioequivalent to GSK's Lamictal Chewables – *i.e.*, that Teva's lamotrigine chewables have the same safety and efficacy as, and are AB-rated to GSK's Lamictal Chewables of the same dosage strength; and (b) Teva's lamotrigine tablets have the same safety and efficacy as, and are AB-rated to GSK's Lamictal Tablets of the same dosage strength.

B. The Patent Litigation and Settlement

57. Soon after GSK's receipt of Teva's paragraph IV certifications to the '017 patent, GSK filed Civil Action No. 02-3779 and Civil Action No. 02-4537 against Teva in federal court in New Jersey in 2002, alleging that Teva's two ANDAs infringed the '017 Patent. The two

patent lawsuits were consolidated in November of 2002. Both suits were filed within 45 days of receipt of the paragraph IV notices from Teva, entitling GSK to automatic 30-month stays of approval of both of Teva's ANDAs. GSK did not file suit against Teva regarding the second patent listed for Lamictal Chewables.

58. Following discovery, the Patent Litigation proceeded to a bench trial before Judge Bissell from January 18 to January 27, 2005. By this time, the 30-month stays of regulatory approval on both of Teva's ANDAs had either expired or were about to expire.

59. On the final day of trial, Judge Bissell orally ruled that claim 1 (the independent claim) of the '017 patent was invalid. He also indicated that a ruling on the validity of the remaining three claims (all dependent claims) would be forthcoming, raising concerns: (1) for Teva, that the ruling could lead to the triggering of its 180-day exclusivity period for its generic version of Lamictal Tablets before Teva had received final FDA approval; and (2) for GSK, that generic entry was imminent for Lamictal Tablets and Lamictal Chewables.

60. The outcome of the Patent Litigation would have directly affected the date on which Teva (and possibly other generics) would be legally permitted to commence sales of their generic lamotrigine products. If GSK were to prevail, then Teva would have been barred from selling its versions of both Lamictal Tablets and Lamictal Chewables until after the expiration of the '017 Patent and any additional exclusivities. On the other hand, if Teva prevailed in demonstrating the '017 patent to be invalid and/or not infringed, then Teva would have been permitted to start selling its products immediately upon FDA approval, which was ultimately granted in 2006. Notably, because Teva was sued under the same patent claims and patent infringement theories for its generic versions of both Lamictal Tablets and Lamictal Chewables, its chances of litigation success were the same for both products.

61. Moreover, the successful invalidation of the '017 patent would dramatically change the competitive landscape for both GSK and Teva in two ways. First, the entry of a final court decision invalidating the '017 patent would start the clock on Teva's 180-day exclusivity period for that patent regardless of whether Teva actually had an FDA-approved product to sell during that period. Thus, the invalidation of the '017 patent would open the floodgates of competition for Lamictal Tablets and Lamictal Chewables because within six months after Teva invalidated the '017 patent, other generics would be able to start selling their AB-rated versions once they received FDA final approval for their respective products. Second, if the '017 patent were invalid, the six-month Pediatric Exclusivity period could not attach to the end of that patent and thus would not be an effective barrier to entry to Teva or the other manufacturers that filed ANDAs to sell generic versions of either Lamictal Tablets or Chewables.

62. In the alternative, assuming a decision from the January 2005 trial in the Patent Litigation was delayed past August 2006 (i.e., past the time Teva received final approval from FDA for its two ANDAs), then Teva could have entered the market "at-risk", thus triggering the start of its 180-day period and allowing any other approved ANDA filers to come to market six months later.

63. The possibility that Teva might have all of the '017 patent claims invalidated posed risks to both GSK and Teva. GSK faced the danger that if the court invalidated the other patent claims, there would be a dramatic reduction in future revenue due to the loss of exclusivity of Lamictal Tablets and Lamictal Chewables. The possibility that Teva might win the trial also placed Teva in a quandary, since a successful final court decision would likely trigger Teva's 180 days of exclusivity for its generic Lamictal Tablets prior to FDA approval, which meant that Teva would not be able to take advantage of some (if any) of its 180-day exclusivity.

As alleged above, Teva's ANDA application for generic lamotrigine chewables did not receive final approval until June 21, 2006 and its ANDA application for generic lamotrigine tablets did not receive Final Approval until August 30, 2006. So, if the January 2005 bench trial resulted in the invalidation of the '017 patent before December 2005, then Teva's 180-day exclusivity would be triggered by a court decision and expire for the both generic Lamictal Tablets and generic Lamictal Chewables before Teva could even bring those products to market. Any other competing generic that had final approval of their ANDAs for generic versions of Lamictal Tablets or Lamictal Chewables as of June 2006 could then enter the market before (or at the same time) as Teva.

64. Thus, GSK had an interest in delaying Teva's entry for as long as possible so that GSK could continue to earn monopoly profits on both Lamictal Tablets and Lamictal Chewables, and Teva had an interest in preventing and/or delaying a successful court decision until it would be in a position to take advantage of its valuable 180-day exclusivity for generic Lamictal Tablets.

65. Recognizing the risks to both parties (i.e., that GSK might lose its patent protection entirely and that Teva might not be ready to take advantage of its success), the parties immediately started settlement negotiations, and on February 2, 2005, the parties had a conference with the court during which they asked the court to refrain from ruling on the validity of the remaining claims.

66. Two weeks following that conference, GSK and Teva reached an agreement, which is set forth in several documents, including a Settlement Agreement between GSK and Teva USA, and a License & Supply Agreement between GSK and Teva Ltd. (the "Settlement"), both of which are dated February 16, 2005. The Settlement Agreement expressly provides that

both the Settlement Agreement and the License & Supply Agreement are part of the "consideration" that GSK offered Teva "in reaching agreement to settle".

67. The Settlement permitted Teva to sell limited amounts of generic lamotrigine chewables in the U.S., starting on June 1, 2005 – approximately 37 months prior to the expiration of the '017 patent. Even though Teva's ANDA to sell its generic version of Lamictal Chewables did not receive final approval from the FDA until June 2006, Teva was supplied by GSK with chewable lamotrigine product which Teva began selling as an authorized generic on May 25, 2005.

68. Under the Settlement, GSK additionally granted Teva: (a) a royalty-free, non-transferable license under the '017 patent to import, manufacture, have manufactured and have sold Teva's generic version of Lamictal Tablets in the United States, starting on July 21, 2008, at 5:00 p.m. Pacific time, which was when the '017 patent expired; and (b) a waiver of any potential pediatric exclusivity applicable to Teva's generic version of Lamictal Tablets. Thus, even though Teva had already succeeded in invalidating the '017 patent's primary, independent claim, and even though there was a significant risk that the patent's other claims might be invalidated, the settlement gave little or no discount or reduction to the patent's exclusionary power (i.e., did not give Teva the right to enter with its generic version of Lamictal Tablets significantly prior to the patent's expiration). Furthermore, even though Teva's generic versions of both Lamictal Tablets and Lamictal Chewables were subject to the same patent claims (and thus, Teva's chances of litigation success were the same for both products), Teva was allowed to start selling a generic version of the smaller $50 million a year product within three months after the settlement, while it agreed to wait at least three years to start selling a generic version of the more than $2 billion a year product. As alleged above, the disparate treatment and entry dates

that GSK and Teva negotiated for the two products (both of which were subject to the exact same patent claims and litigation risks) reflects the fact: (a) that the parties did not choose (or even attempt to choose) entry dates for the two products that reasonably reflected the probability that all of the asserted claims of the '017 patent were invalid; and (b) the parties were not concerned about whether the agreement would keep Teva off the market for the larger product longer than was warranted by the patent. Rather, it reflects the reality that Teva was paid financial compensation to delay entry of its generic Lamictal Tablet product. Furthermore, while the negotiated deal benefitted Teva and GSK, it was not done with any concern or interest for purchasers or consumers.

69. Because Teva's generic versions of Lamictal Chewables were AB-rated only to the low-dosage strength branded Lamictal Chewables and were not AB-rated to Lamictal Tablets, Teva could not, prior to July 2008, provide lower-priced generic substitutes for Lamictal Tablets that would: (1) be broadly substituted for the higher-priced Lamictal Tablets, or (2) otherwise efficiently compete with Lamictal Tablets. Accordingly, the purchaser/consumer benefits gained by the early generic Lamictal Chewable entry date of June 2005 pale in comparison to the purchaser/consumer harm incurred by the anticompetitive three-year delay in the entry of Teva's less-expensive generic version of Lamictal Tablets.

70. Teva received significant consideration, incentives, and benefits in exchange for its agreement to: (a) abandon its efforts to invalidate the '017 patent; and (b) not start competing against GSK's Lamictal Tablets with a less-expensive generic version until the '017 patent expired. First, Teva was permitted to enter the U.S. market within a few months with an authorized generic version of the much smaller, $50 million per year Lamictal Chewables. In pleadings from a subsequent Teva-GSK litigation, GSK acknowledged that its agreement

allowing Teva to enter in three months with a generic version of the smaller Lamictal Chewable product "formed part of the bargain between GSK and Teva" and was one of the "benefits" that Teva received for agreeing to abandon its efforts to invalidate the '017 patent and to stay off the market with the larger Lamictal Tablet product for at least three years.

71. The second consideration and incentive that Teva received for: (a) dropping its efforts to invalidate the '017 patent; and (b) not starting to compete against GSK with a generic Lamictal Tablet until the '017 patent expired, was an illegal, anticompetitive agreement in which Teva would be virtually guaranteed the right to use all or most of its 180-day exclusivity periods for both Lamictal Tablets and Lamictal Chewables, which would enable it to charge higher prices during those periods, and to maximize its longer-term profits by obtaining the "first mover advantage." This also benefitted GSK since the fact that Teva would charge higher prices during the first 180 days meant that there would be less competitive pressure on GSK during this period, such that it would lose less market share during this period than if there were multiple generics in the market during the period. GSK was also benefitted in a broader sense in that the agreements as a whole delayed not only the entry of Teva but other generics as well. Thus, by and through these agreements, Teva and GSK afforded themselves a guarantee of higher revenues during these periods of time which resulted in anticompetitive overcharges being thrust upon purchasers.

72. In addition to the above incentives provided to Teva for its delayed launch of a Lamictal Tablet generic, GSK agreed to not exercise its lawful right to launch a competing authorized generic during the first six months that Teva was on the market with its generic versions of Lamictal Tablets and Lamictal Chewables. At the time these agreements were drafted, a pharmaceutical company such as GSK that marketed a brand-name drug under an

NDA would often introduce – either by itself or through an affiliate – an authorized generic at the same time or just before the first third-party generic came to market. An authorized generic is marketed under the NDA for the original brand-name drug, instead of another company's ANDA, but carries generic trade dress and prices. The purposes for marketing an authorized generic include: (1) lowering the market share captured by the third-party generic company; and (2) recouping some of the profits lost through the steep decline in sales of the original brand-name drug upon generic entry.

73. A brand company's launch of an authorized generic is extremely damaging to any first-filer generic, such as Teva, because it results in lost market share (i.e., fewer units sold), reduced profits because price competition between the generic and authorized generic forces down prices, and a reduction in the generic's long-term "first mover advantage." As the FTC noted in a June 2009 report on Authorized Generics, "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [Authorized Generic] enters the market, due to the greater discounting that accompanies the added competition provided by the [Authorized Generic]."

74. Notably, while a brand company can lower the prices on its brand products instead of launching an authorized generic (which was an option left open to GSK under the Settlement), that option does not present the same danger to a generic such as Teva, and does not result in the same savings to purchasers. This is because many states have regulations that either require or strongly encourage pharmacists to automatically fill prescriptions with only an AB-rated generic version of a drug in most situations. Thus, even if an NDA holder (such as GSK) lowers the price of its brand drug, state regulations are a barrier that prevent or impede the branded drug from being used for most prescriptions. The result is that most of a generic's sales

volume is unaffected by a reduction in the brand price and the generic does not feel the competitive pressure to lower its prices in response to a drop in the branded price (in contrast to the situation where a branded company launches an authorized generic). Thus, while an NDA holder can try to compete against a generic drug through various means other than launching an authorized generic, those competitive options are far weaker and do not provide nearly the consumer savings and benefits as the launch of a true authorized generic. Consequently, GSK's agreement to restrict its competitive responses to far less effective, secondary options was an illegal, anticompetitive agreement by which the parties agreed to restrict competition that would undermine Teva's prices during the first 180 days of sales, and consequently resulted in overcharges to purchasers.

75. Indeed, in its June 2009 report regarding Authorized Generics, the FTC expressly concluded that a generic manufacturer might agree to delay the sale of its generic product in exchange for a brand company's agreement (such as the one involved here) to not launch an authorized generic to consumers' detriment:

> To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement not to launch an authorized generic – that is, a brand's agreement not to compete with the generic through an AG – during the generic's 180 days of marketing exclusivity…Such agreements can harm consumers in two ways…"

76. According to Teva's pleadings in a 2008 litigation regarding these products, during the settlement negotiations GSK and Teva specifically considered the possibility that GSK might want to sell an authorized generic during Teva's six-month exclusivity periods, but the parties agreed that GSK would not be permitted to do so. According to Teva, GSK's agreement to not launch an authorized generic during the first six months that Teva was selling generic Lamictal Tablets was a critical and central consideration for Teva's acceptance of the

settlement and delayed entry dates for generic Lamictal Tablets. For example, Teva stated in the 2008 litigation, that GSK's agreement to not compete against Teva by selling an authorized generic during the first 180 days in which Teva was selling generic Lamictral Tablets was:

> **[A]n important component of the settlement between the parties and formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation**.
>
> * * *
>
> …the **key consideration** Teva bargained for in [the License and Supply Agreement.]

Thus, according to Teva, GSK's agreement to not launch an authorized generic was a "key" and "important" consideration of Teva's decision to relinquish its attacks on the '017 patent's validity.

77. Absent GSK's illegal agreement to refrain from competing against Teva by selling an authorized generic during the first 180 days (and absent payment of the other financial consideration alleged above), Teva would have insisted on an entry date for its generic version of Lamictal Tablets earlier than the the entry date it accepted in the Settlement. As Teva acknowledged in its pleadings in the subsequent litigation, Teva believed that GSK's agreement to not launch an authorized generic was critical because Teva was only getting a short period of time to sell its generic Lamictal Tablet product before other generics were free to enter the market. As Teva stated, GSK's agreement to refrain from competing against Teva by selling an authorized generic during the first 180 days was:

> **[C]ritical here, because the benefit conferred to Teva from this License Agreement was of such a short duration**. GSK's pediatric exclusivity under its patent was to expire on January 22, 2009. . . . Thus, **the benefit to Teva of the License Agreement was a brief, six-month window in which it would be the first and only supplier of generic lamotrigine**.
>
> * * *

> That the parties would agree on this is perfectly sensible given **the short duration** of Teva's exclusive rights and given the known industry practice under which pharmaceutical companies sometimes launched generics of their own branded products.

78. On April 4, 2005, the parties filed a Stipulation and Order of Dismissal in the Patent Litigation seeking the dismissal of all claims and counterclaims. On the same day the court signed the dismissal, it also entered an order withdrawing the bench ruling that invalidated claim 1 of the '017 patent.

C. Teva's Exclusive Launch of Generic Lamotrigine Tablets

79. Despite having received FDA approval to launch lamotrigine tablets almost two years earlier, Teva delayed launching its generic version of Lamictal Tablets until on or about 5:00 p.m. Pacific time on July 21, 2008 (the earliest date permitted under the terms of the agreement with GSK).

80. Pursuant to the agreement between GSK and Teva, GSK did not launch a true authorized generic during the Teva's exclusivity period for its generic version of Lamictal Tablets, nor did GSK launch an authorized generic during Teva's previous exclusivity period for its generic version of Lamictal Chewables.

81. Although Teva has alleged that GSK implemented a scheme to slow Teva's market penetration for its generic version of Lamictal Tablets through the use of DAW 5 codes and discounts to certain retailers, none of GSK's conduct had the effect of constraining or reducing the pricing of Teva's generic Lamictal Tablets during the exclusivity period in the same way that competition from a true authorized generic would.

82. On information and belief, this generic market exclusivity and accompanying supra-competitive pricing generated many millions of dollars of additional revenue for Teva

during the six-month exclusivity periods at the expense of purchasers who would have paid lower prices for Teva's generic lamotrigine tablets had GSK launched an authorized generic.

83. Because of Teva's 180-day exclusivity on generic versions of Lamictal Tablets, which was secured by and through the anticompetitive agreements at issue, no other generic was allowed to launch, and none in fact did launch, prior to January 22, 2009.

D. Defendants' Conduct Delayed Generic Competition and Enabled Defendants To Wrongfully Charge Supra-Competitive Prices for Lamotrigine Tablets.

84. Teva's 180-day exclusivity period for its generic version of Lamictal Tablets would have been triggered earlier if: (a) Teva and GSK had settled without the provision of illegal financial inducements to Teva from GSK, which would have resulted in a settlement that provided for an earlier entry of Teva's less expensive generic version of Lamictal Tablets; and/or (b) Teva had launched its generic Lamictal Tablet product (as they would have) upon receipt of final FDA approval in August 2006, either "at-risk" or after successfully invalidating the '017 patent. Instead, because of the unlawful agreements, Teva did not enter until July 2008, leaving their 180-day exclusivity in place and thereby blocking final FDA approval and entry of other generic versions of Lamictal Tablets until January 2009.

85. The agreement between Teva and GSK guaranteed that Teva's generic exclusivity period would not be triggered on the Lamictal Tablet ANDA by a final court decision in the Patent Litigation before Teva received FDA approval of that ANDA, and ultimately provided Teva with a full 180-days of exclusive generic sales on that product.

86. The agreement between Teva and GSK guaranteed that GSK would have exclusivity on the blockbuster Lamictal Tablet product with no generic competition for more than three years from the date of the Settlement.

87. In exchange for Teva's delaying its launch of its generic version of the blockbuster Lamictal Tablet until close of business on July 21, 2008, Teva secured: (1) the right to immediately launch a generic equivalent of the Lamictal Chewable product, which generated some limited profit for Teva, but created much smaller consumer savings and benefits than an earlier launch of the blockbuster Lamictal Tablet product (i.e., the consumer welfare generated by the earlier launch of generic lamotrigine chewables pales in comparison to the consumer harm created by the anticompetitive delay in entry of the generic lamotrigine tablets); (2) a virtual guarantee on its ability to sell during the 180-day exclusivity period relating to its generic version of Lamictal Tablets; and (3) GSK's agreement to not use its most effective means of competing against Teva during their 180-day exclusivity periods for both Lamictal Tablets and Lamictal Chewables by marketing a true authorized generic.

88. Defendants' unlawful conduct, therefore, delayed not only the launch of less expensive generic versions of Lamictal Tablets, but prevented GSK's launch of authorized generic products in competition with Teva's generic versions of Lamictal Tablets and Lamictal Chewables during the applicable exclusivity periods.

89. Moreover, the agreements between GSK and Teva which delayed Teva's launch of the generic Lamictal Tablets and guaranteed Teva's exclusivity period on that product without competition from a GSK authorized generic were not necessary for the settlement of the Patent Litigation and constitute ancillary restraint of trade.

VII. EFFECT ON INTERSTATE COMMERCE

90. At all material times, Lamictal Tablets and Lamictal Chewables, manufactured and sold by GSK, and generic versions of Lamictal tablets manufactured by Teva, were shipped across state lines and sold to customers located outside its state of manufacture.

91. During the relevant time period, in connection with the purchase and sale of Lamictal Tablets and Lamictal Chewables (and Teva's generic versions of those products), monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

92. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

VIII. RELEVANT MARKET

93. Direct proof exists that GSK had monopoly power over the price of lamotrigine tablets and their AB-rated generic equivalents. Such direct evidence will include, *inter alia*: (a) manufacturers' and/or market-wide transactional data that will show a significant, non-transitory decline in lamotrigine tablet prices upon entry of AB-rated generic lamotrigine tablets that had not occurred until generic entry; and (b) abnormally high price-cost margins enjoyed by GSK prior to the entry of such generic competition. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether GSK had monopoly power.

94. Assuming, *arguendo*, that a relevant market needs to be defined, the relevant product market is all lamotrigine tablet products – i.e., Lamictal Tablets (in all its forms and dosage strengths), and AB-rated equivalent lamotrigine products. In the alternative, the relevant market is defined as all lamotrigine products – i.e., all Lamictal brand products and their AB-rated generic equivalents. The relevant geographic market is the United States and its territories. A firm that was the only seller of such products in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price

increase unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it lacked generic competition. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which lamotrigine products are prescribed.

95. Through the anticompetitive conduct alleged herein, Defendants were able to profitably charge supra-competitive prices for lamotrigine tablet products without losing substantial sales, and thus, by definition, maintained monopoly power with respect to lamotrigine tablet products sold in the United States.

96. GSK's market share in the relevant market is 100%.

IX. FIRST CAUSE OF ACTION VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. §1)

97. Plaintiff incorporates and re-alleges Paragraph's 1-96 in this Complaint, as though fully set forth below.

98. Beginning in or about January 2005 and continuing through January 2009, GSK and Teva engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of lamotrigine tablets in the United States to GSK until July 21, 2008; (b) fix the price at which Plaintiff and the other members of the Class would pay for lamotrigine tablets at the higher, branded price during that period; and (c) prevent the sale of generic versions of lamotrigine tablets other than Teva's (including GSK's authorized generic versions) in the United States until at least January 22, 2009.

99. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. §1. Defendants' agreements are horizontal market allocation and price fixing agreements

between actual or potential competitors and thus are *per se* violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1 when viewed under a "quick look" or "rule of reason" mode of analysis.

100. Plaintiff and all members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiff and the Class members have paid more for their purchases of Lamictal Tablets and/or Teva's generic lamotrigine tablets than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive Lamictal Tablets and/or Teva's generic equivalent.

101. As a result of Defendants' illegal conduct, Plaintiff and the Class paid more than they would have paid for lamotrigine tablets, absent Defendants' illegal conduct. But for Defendants' illegal conduct, competitors would have begun marketing AB-rated generic versions of lamotrigine tablets well before July 2008 (including GSK through the launch of an authorized generic), and/or would have been able to market such versions more successfully.

102. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiff and other Class members would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets and/or Teva's generic lamotrigine tablets for some or all of their lamotrigine requirements, and/or would have paid lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalent**.**

103. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalent

directly from Teva. As a result of the Defendants' illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiff and the other Class members paid prices for lamotrigine tablets that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of brand-name Lamictal Tablets was artificially inflated by Defendants' illegal conduct.

X. SECOND CAUSE OF ACTION
VIOLATION OF SECTION 2 OF THE SHERMAN ACT AGAINST GSK
(15 U.S.C. § 2)

104. Plaintiff incorporates and realleges Paragraph's 1-103 in this Complaint, as though fully set forth below.

105. Defendant GSK used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the lamotrigine tablet market, as detailed above.

106. GSK combined, conspired and contracted with Teva to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and GSK did in fact monopolize trade in the United States in the market for lamotrigine tablets, and to eliminate competition in the sale of Lamictal Tablets and its generic equivalents in the United States.

107. The goal, purpose and/or effect of GSK's scheme was also to maintain and extend GSK's monopoly power with respect to lamotrigine tablets. GSK's illegal scheme to prevent, delay and/or minimize the success of the introduction into the United States marketplace of any generic version of Lamictal Tablets enabled GSK to continue charging supra-competitive prices for lamotrigine tablets without a substantial loss of sales.

108. As a result of GSK's illegal conduct, Plaintiff and the Class paid more than they would have paid for lamotrigine tablets, absent GSK's illegal conduct. But for GSK's illegal conduct, competitors would have begun marketing AB-rated generic versions of Lamictal Tablets well before July 2008 (including GSK through the launch of an authorized generic), and/or would have been able to market such versions more successfully.

109. If manufacturers of AB-rated generic lamotrigine tablets entered the market and competed with Lamictal Tablets in a full and timely fashion (including GSK through the launch of an authorized generic), Plaintiff and other Class members would have substituted lower-priced generic lamotrigine tablets for the higher-priced brand-name Lamictal Tablets for some or all of their lamotrigine tablet requirements, and/or would have received lower prices on some or all of their remaining purchases of GSK's Lamictal Tablets and/or Teva's generic equivalent.

110. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Lamictal Tablets directly from GSK and/or their generic equivalent directly from Teva. As a result of GSK's illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their lamotrigine tablet requirements. Plaintiff and all of the other Class members paid prices for lamotrigine tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the

opportunity to purchase lower priced generic lamotrigine tablets instead of expensive brand-name Lamictal Tablets; (2) Class members were forced to pay artificially inflated prices for generic lamotrigine tablets; and/or (3) the price of branded Lamictal Tablets was artificially inflated by GSK's illegal conduct.

111. GSK's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for lamotrigine tablets in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, prays for judgment against all Defendants, jointly and severally, as follows:

1. That the Court adjudge and decree that the Defendants and each of them have violated Sections 1 and 2 of the Sherman Antitrust Act;

2. That the Plaintiff and all others similarly situated be awarded damages suffered by reason of these violations and that those damages be trebled in accordance with the law;

3. That the Plaintiff be awarded reasonable attorneys' fees and costs;

4. That any and all rights that Teva may have under the Hatch-Waxman Act be declared null and void and of no further effect; and

5. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

DATED: February 17, 2012

Respectfully Submitted,

s/ Peter S. Pearlman
PETER S. PEARLMAN
COHN LIFLAND PEARLMAN
HERRMANN & KNOPF LLP
Peter S. Pearlman
Park 80 Plaza West-One
250 Pehle Avenue, Suite 401
Saddle Brook, NJ 07663
201-845-9600
psp@njlawfirm.com

GARWIN GERSTEIN & FISHER LLP
Bruce E. Gerstein
Joseph Opper
Ephraim R. Gerstein
1501 Broadway, Suite 1416
New York, NY 10036
Tel: (212) 398-0055
Fax: (212) 764-6620

ODOM & DES ROCHES, L.L.P.
Stuart E. Des Roches
Andrew W. Kelly
Chris Letter
650 Poydras Street
Suite 2020
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078

SMITH SEGURA & RAPHAEL, LLP
David C. Raphael, Jr.
Erin R. Leger
3600 Jackson Street, Suite 111
Alexandria, LA 71303

Tel: (318) 445-4480
Fax: (318) 487-1741

HEIM, PAYNE & CHORUSH, L.L.P.
Russ Chorush
600 Travis, Suite 6710
Houston, Texas 77002
Tel: (713) 221-2000
Fax: (713) 221-2021